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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/615,510

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

11/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/615,510	Applicant(s) KLINT, HENRIK S.	
	Examiner JONATHAN ML FOREMAN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/2/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 2,7,8,10-18,20,21 and 23-28,35 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9,19,22 and 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 35 and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/1/08.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3 - 5, 19, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,748,986 to Morrison et al.

In regard to claims 1, 3 - 5, 19, 29 and 30, Morrison et al. disclose a body portion (Figure 4) having a first diameter and comprising a multiple filament group of individual wire coils wound adjacent to one another (Col. 3, lines 27 – 30; Col. 4, lines 36 – 41), defining an open lumen (Figure 4); a distal end portion having a substantially constant second diameter along a distance of at least four wound wire coils (Figure 4), wherein the second diameter that is less than the first diameter; a taper portion having a taper from the first diameter to the second diameter; and a coating disposed over the distal end portion, taper portion, and at least a part of the body portion (Col. 3, lines 8 – 10). The coating comprises an elastic low-friction coating (Col. 3, lines 8 – 10) that defines a taper adjacent the taper portion in that the coating is applied to the taper portion.

4. Claims 31 – 34 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,178,158 to de Toledo.

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In regard to claims 31 – 34, de Toledo discloses an elongate medical device (Figure 3) including an elongate shaft including a body formed as a helically-wound single file row of a plurality of abutting wires (Col. 4, lines 42 – 45) defining an open shaft lumen (22); an external sealing coating providing the lumen with a leakproof seal (Col. 5, lines 33 - 37); and a distal shaft portion that is more flexible than a proximal shaft portion (Col. 4, lines 54 - 56). The outer diameter of the distal shaft portion is less than an outer diameter of the proximal shaft portion (Figure 3).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,748,986 to Morrison et al. in view of U.S. Patent No. 5,980,471 to Jafari.

In regard to claim 6, Morrison et al. disclose the guidewire having a coating comprising a low-friction coating such as Teflon (Col. 3, lines 8 – 10), but fail to disclose the coating being a hydrophilic material. Jafari disclose a guidewire having a low-friction coating including Teflon or a hydrophilic material (Col. 6, lines 37 – 42). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the Teflon coating disclosed by Morrison et al. with the hydrophilic material as taught by Jafari in that Jafari teach a Teflon coating and a coating including hydrophilic material as being functionally equivalent and therefore interchangeable. Additionally, the claim would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the

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invention. Because both Morrison et al. and Jafari teach low-friction coatings for use on a guidewire, it would have been obvious to one skilled in the art at the time of the invention to substitute one coating for the other to achieve the predictable results of reducing drag on the guidewire during insertion into a body.

7. Claims 1, 4, 5, 9, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,178,158 to de Toledo in view of U.S. Patent No. 5,961,511 to Mortier et al..

In regard to claims 1, 4, 5, 9, 19 and 22, Morrison et al. teach a guidewire (Abstract) including a proximal body portion (11) having a first diameter and comprising a multiple filament group of individual wire coils wound adjacent one another (Col. 4, lines 42 – 45), defining an open lumen (22); a distal end portion (13) having a substantially constant diameter along a distance of at least four wound wire coils, and an elastic low-friction coating (40) disposed over the distal end portion and at least a part of the proximal body portion. De Toledo discloses the distal portion having a flexibility greater than the proximal portion (Col. 4, lines 54 - 57). However, de Toledo fails to disclose the proximal portion having a first diameter and the distal portion having a second diameter less than the first a taper portion having a taper from the first diameter to the second diameter. Mortier et al. teach a medical device (Figure 10C) having a proximal portion (130) having a first diameter, a distal portion (132) having a second diameter smaller than the first diameter and a tapered portion (138) having a taper from the first diameter to the second diameter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as disclosed by de Toledo to include a tapered portion between the proximal portion and a distal portion to create a transition section having a flexibility between that of the proximal section and the distal section (Col. 10, lines 37 – 39). Creating a tapered portion would result in the

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multiple-filament group of wire coils forming the taper being wound at a pitch angle different than a pitch angle of a multiple-filament group of individual wire coils of a body portion.

Response to Arguments

8. Applicant's arguments filed 7/2/09 have been fully considered but they are not persuasive. Applicant asserts that the wound wire shaft of Morrison et al. is not open in that it requires an elongate core element to occupy the space within the coils. However, the Examiner disagrees. The elongate core element does not occupy the entire space within the lumen formed by the coils, thus the coils define an open lumen (Figure 4).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736